

GEERKE et al.

Serial No.: 09/324,343

Filed: June 2, 1999

For: METHODS AND APPARATUS FOR DETERMINING FORMULATION ORIENTATION OF MULTI-LAYERED PHARMACEUTICAL DOSAGE FORMS

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formulating a non-drug ingredient containing third layer [formulation] comprising [containing] a second colorant that is distinguishable [by said color detector] from the [said] first colorant or from no color and not containing any drug ingredient; [and]

Back B1 Cont

compressing the [said] first, second and third layers into a capsule-shaped osmotic tablet wherein [having] the [said] first layer [formulation] is located at one end of the capsule shaped osmotic tablet and the [said] third layer [formulation] is located at the other end of the capsule shaped osmotic tablet and the [having said] second layer is located [in] between the first layer and the third layer such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored [formulation] layer depending on the formulation orientation of the tablet; and

detecting the formulation orientation of the tablet with a color detector directed at a spot location on the side of the tablet.

19. **(Amended)** The method of claim 18 wherein the [said] first colorant is light and the [said] second colorant is dark.

20. **(Amended)** A method of making a three-layer tablet [that contains color indicators for detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet, the method] comprising [the steps of]:

formulating a first layer [formulation] containing a drug ingredient and not containing any colorant;

formulating a second layer [formulation] containing a drug ingredient and a first colorant, the [said] first colorant being complementary to no color;

formulating a third layer [formulation] containing a second colorant that is distinguishable [by said color detector] from the [said] first colorant or from no color and not containing any drug ingredient; [and]

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compressing the [said] first, second and third layers into a capsule-shaped osmotic tablet wherein [having] the [said] first layer [formulation] is located at one end of the capsule shaped osmotic tablet and the [said] third layer [formulation] is located at the other end of the capsule shaped osmotic tablet and the [having said] second layer is located [in] between the first layer and the third layer such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored [formulation] layer depending on the formulation orientation of the tablet; and

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detecting the formulation orientation of the tablet with a color detector directed at a spot location on the side of the tablet.

21. (Amended) A method of making a multi-layer tablet [that contains color indicators for detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet, the method]comprising [the steps of]:

adding a first colorant to one formulation layer containing a drug ingredient proximately [to be] positioned [in the proximity of] at a dispensing end of the multi-layered tablet, the [said] first colorant being complementary to no color;

adding a second colorant to at least one formulation layer not containing any drug ingredient proximately [to be] positioned at a push end of the multi-layered tablet, the [said] second colorant distinguishable [by said color detector] from the [said] first colorant or from no color; [and]

compressing the formulation layers into a capsule-shaped osmotic tablet such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet; and

detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet.

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22. (Amended) A three-layer tablet [that contains color indicators for detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet, the tablet] comprising:

a first layer formulation containing a drug ingredient and a second layer containing a drug ingredient, one of the [said] first or second layers also containing a first colorant;

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a third layer formulation containing a second colorant that is distinguishable [by said color detector] from the [said] first colorant or from no color and not containing any drug ingredient wherein the [said] first, second and third layers are compressed into a capsule-shaped osmotic tablet having the [said] first layer formulation located at one end of the capsule shaped osmotic tablet and the [said] third layer formulation located at the other end of the capsule shaped osmotic tablet and the [having said] second layer located [in] between the first layer formulation and the second layer formulation such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet and wherein the formulation orientation of the tablet is detected by a color detector directed at the spot location on the side of the tablet.

23. (Amended) The tablet of claim 22 wherein the [said] first colorant is light and the [said] second colorant is dark.

9

24. The tablet of claim 23 further comprising a membrane surrounding the compressed layers through which the first and second colorant are detectable.

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25. (Amended) The tablet of claim 24 further comprising a delivery port drilled into the [said] membrane at a location proximate to the [said] first layer.

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26. The tablet of claim 25 further comprising a drug overcoat applied onto the surface of the membrane.

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27. (Amended) A three-layer tablet [that contains color indicators for detecting the formulation orientation of the tablet with a color detector directed at a spot location on a side of the tablet, the tablet] comprising:

a first layer formulation containing a drug ingredient and not containing any colorant;

Sub B1 Cont
a second layer formulation containing a drug ingredient and a first colorant, the [said] first colorant being complementary to no color;

a third layer formulation containing a second colorant that is distinguishable [by said color detector] from the [said] first colorant or from no color and not containing any drug ingredient wherein the [said] first, second and third layers are compressed into a capsule-shaped osmotic tablet wherein the [having said] first layer formulation is located at one end of the capsule-shaped osmotic tablet and the [said] third layer formulation is located at the other end of the capsule-shaped osmotic tablet and the [having said] second layer is located [in] between the first layer formulation and the third layer formulation such that the formulation orientation of the tablet can be determined by detecting the color at a spot location on a side of the tablet corresponding to one or another differently-colored formulation layer depending on the formulation orientation of the tablet; and wherein the formulation orientation of the tablet is detected by a color detector directed at the spot location on the side of the tablet

28. (Amended) The tablet of claim 27 wherein the [said] first colorant is light and the [said] second colorant is dark.

29. The tablet of claim 28 further comprising a membrane surrounding the compressed layers through which the first and second colorant are detectable.